

OPP OFFICIAL RECORD  
HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

OPP OFFICIAL RECORD  
HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 361

PC  
790221 Ch misty Branch

~~Ch misty Branch~~  
~~Branch~~  
~~Branch~~  
File: OPP 1F1052

August 30, 1971

Pesticide Petition No. 1F1052

Mr. M. M. Gladstone  
Vice President, Technical Liaison  
Organics Division  
Witco Chemical Corporation  
400 North Michigan Avenue  
Chicago, Illinois 60611

Dear Mr. Gladstone:

This replies to your letter of August 18, 1971, inquiring as to the status of Pesticide Petition No. 1F1052 requesting exemption from requirement of a tolerance for the emulsifier N-(amino-ethyl) ethanolamine salt of dodecylbenzene sulfonic acid when used in liquid emulsifiable herbicide concentrates.

The petition is still being reviewed by our scientists. In the meantime, the emulsifier may continue to be used in pesticide formulations.

Sincerely yours,

Lee E. TerBush  
Petitions Control Officer  
Petitions Control Branch  
Pesticides Tolerances Division

cc:  
PRD, EPA

cc:  
PTD  
Chemistry Branch  
Toxicology Branch  
OGFitzhugh

LETerBush:ea 8/30/71  
R/D Init:DMBaker 8/26/71

SEP 1 1971

End  
of  
Document

**Witco  
Chemical***Chem. Br*

August 18, 1971

~~*Amery*~~  
~~*B. C.*~~  
~~*W. J.*~~  
~~*W. J.*~~*1F1052*

Pesticide Tolerances Division  
Environmental Protection Agency  
South Agriculture Building  
Washington, D. C. 20250

Attn: Mr. Drew M. Baker

Reference: Pesticide Petition No. 1F1052

Dear Mr. Baker:

I submitted two petitions, 1F1043 and 1F1052, on  
September 15, 1970 and October 5, 1970, respectively.

I received a letter from EPA on 1F1043, dated June 9, 1971,  
requesting additional information (which has been answered).

However, I have not yet heard anything about 1F1052. Since  
the two petition numbers are so close together, I am a little  
concerned, particularly since some customers are asking  
about the current status of the products affected by 1F1052.

Am I correct in assuming that our customers may continue  
to use the products affected by 1F1052 pending final action?

Could you give me a rough estimate of when EPA might act  
on this petition?

Very truly yours,

WITCO CHEMICAL CORPORATION

*M. M. Gladstone*  
M. M. Gladstone  
Vice President  
Technical Liaison  
Organics Division

MMG/aes

End  
of  
Document

May 14, 1971

Fish and Wildlife Opinion

Mr. Charles L. Smith, Head  
Petitions Control Section, PRD

In accordance with the discussion between Mr. H. G. Alford, Mr. F. J. McFarland, Mr. Devaney, and ourselves on May 13, 1971, we are nearing the end of our review of the following petitions and would appreciate a comment that the proposed tolerance or exemption would not be objectionable from the standpoint of effect on fish and wildlife for each of the following:

OF0924

OF0963

1E1017

1F1026

1F1028

1F1029

1F1034

1F1036

1F1044

1F1052

Thank you,

Drew M. Baker, Jr., Chief  
Petitions Control Branch  
Pesticide Tolerances Division  
cc:

each petition

PTD Chemistry Br. Toxicology Br. Dr. Fitzhugh

DMBaker:mbc 5/14/71

Chem. Bu

Li: OP # 1F1052

*Chem Comment required  
9/22/71  
6/2/71*

*Cummings  
Banks*

May 11, 1971 *tot*

We wish to draw attention to the following observations in regards to the following two petitions:

Mr. Owen M. Baker  
Pesticides Tolerances Division

*File: PP# 1F1052  
In duplicate  
Duffy  
G.D.*

Pesticide Petition Nos. 1F1052

1F1043

Petitioner: Witco Chemicals

Witco Chemicals

Name of Emulsifiers:  
N(aminoethyl)ethanolamine  
salt of dodecyl benzene  
sulfosuccinic acid

A mixture of 4,  
comparable compounds  
(Emcol HA, H2A, H3A  
and H12A)

Formulation designation:  
Emcol P-1052M

AC56-14

Use levels in formulations:  
3-6%

0.2%

Residue estimates as per PES memos:  
"negligible range if  
present at all"  
2/5/71

1 ppm for each  
component Emcols  
3/16/71

Use Limitation: "pre-emergence or very early in the growing season"

Toxicity data: Acute oral LD<sub>50</sub>

Acute oral LD<sub>50</sub>  
two 90-days rat and  
dog. With undefinable  
no effect level, but  
less than 1000 ppm.

Based on Petitions Evaluation Branch memos, we had found the use (our memo 4/26/71) of Emcol P-1052M as safe and suitable for regulation. The basis for safety rested on negligible residues in crop foods. For the AC56-14, (PP 1F1043) the toxicity data is not satisfactory to issue a regulation. Both the estimates of residues were arrived at on theoretical considerations and no actual estimates were provided by the petitioner.

PP #s 1F1052 &amp; 1F1043

- 2 -

In this context we wish to draw attention, that we are seriously concerned in learning the "amounts, and chemical nature of residues (parent or derived chemicals) that could be left on the crop reacted or unreacted and could become component of human diet". Thus, the inerts need not be looked too lightly, as some of these are moderately toxic compounds. The final compound is a neutralization product of an acid, alcohol and base, and could very well be hydrolyzed into basic constituent components. The amines as well as alcohols in these cases are of considerable concern for us from toxicity point of view. We therefore seek a better estimate and in depth appraisal of the residues of inert chemicals as well, for safety considerations. The effect of residues on forage crops or hay need be also kept in mind and given some consideration for an overall safety evaluation purpose. Thus whenever there are some complex inert additives requested for inclusion under 420.1001 or as adjuvants to pesticidal formulations, we need a clear chemical structural identity of the proposed compound(s), its purity specifications, and their potential residual levels on crop foods or in human diet.

In view of the above, we suggest, a further residual evaluation be made on PP 1F1052 and PP 1F1043 which would be in harmony and could form the basis for safety consideration.

We have drawn attention of Mr. George Beusch and upon hearing from him we will make further evaluations of the proposals in PP 1F1052 and PP 1F1043.

Krishna P. Misra, Ph.D.  
Toxicology Branch  
Pesticides Tolerances Division

cc:  
OGFitzhugh  
JCCummings ✓  
Perrine Sr.  
Atlanta Sr. (C Lewis)  
PRD/EPA  
PP #s 1F1052 & 1F1043

KPMisra/ccw  
5/11/71

End  
of  
Document

*Cummings*  
*Burch*

Proposal to include under 420.1051(d) Exemptions from the requirements of a tolerance "N-(aminoethyl)-ethanol amine salt of dodecyl benzene sulfonic acid" as a surfactant component of herbicidal formulations for use at "preemergence or very early in the growing season" of crops

April 26, 1971

*Walt*  
*et*

Mr. Drew H. Baker  
 Pesticides Tolerances Division

*File: PP 1F-1052*

Pesticide Petition No. 1F-1052  
 (Evaluation of 10/5/70 submission)

Nitco Chemical Corporation  
 400 North Michigan Avenue  
 Chicago, Ill. 60611  
 (AF 11-129)

N-(aminoethyl)ethanolamine salt of dodecyl benzene sulfonic acid (trade name Emcol P-1052H) is described as produced by the neutralization of dodecyl benzene sulfonic acid with N-(aminoethyl)ethanolamine ( $\text{CH}_2, \text{CH}_2, \text{NH}_2, \text{CH}_2, \text{CH}_2, \text{OH}$ ) at a pH of 4.9-5.1. It is proposed to be used at 3 to 6% of the formulation with an application rate of about 13.6 gm/acre or 0.32 mg/sq. ft. of the salt or as 1.9 gm/acre or 0.05 mg/sq. feet of the N-(aminoethyl)ethanolamine.

The Petitions Evaluations Branch stipulates (memo of 2/5/71), on theoretical basis, that the residues would be in the "negligible range if present at all". The petitioner has not given any actual residual data rather than a theoretical estimate is provided in this petition.

The petition contains an acute oral  $\text{LD}_{50}$  for Emcol P-1052H (a 75% active compound in 25% n-propanol) as 1700 (400-6205) mg/kgm for female rats and 3161 mg/kgm for male (Hazelton Lab. summary) rats.

#### Evaluation

Earlier (our memo of 11/2/66 in PP7ED-886) we could not entertain a broader proposal for aminoethylamine ethanolamine dodecyl benzene sulfonate as supportive safety data was lacking. Emcol P-1052H or N-(aminoethyl)ethanolamine salt of dodecyl benzene sulfonic acid was proposed by Nitco Chemicals, and we were unable to document safety (our memo of 9/17/69) under conditions of its residues in food crops.

We have in our files acute data on N-(2-aminoethyl)ethanol amine as follows:

(FAP# 1489,  $\text{NH}_2, \text{CH}_2, \text{CH}_2, \text{NH}_2, \text{CH}_2, \text{CH}_2, \text{OH}$ ):

Acute oral  $\text{LD}_{50}$ , rat 3 gm/kgm

Acute skin penetration  $\text{LD}_{50}$ , rabbit, 3.56 ml/kgm

Acute inhalation exposure, 6-hours, of saturated vapor killed 0/6 rats.

PP #1F -1052

- 2 -

Acute eye irritation (rabbit) classed the chemical as "moderately irritating."

Acute skin irritation: was mild in effect.

It may be pointed out that N-(2-aminoethyl)ethanol amine is different from ethanolamines (mono-, di- and tri- compounds) and 2-b-ethylaminoethanol (Hartung et al. Food Cosm. & Toxl. 7, 295, 1969).

Dodecyl benzene sulfonic acid is allowed under 126.1031 and 127.2341 and we have toxicity data (Chronic on Monsanto's Santomers in FAPs 1042, 1043, & 1044).

### Conclusion

While we do not have adequate long term oral feeding data on N-(2-aminoethyl)ethanol amine, or its dodecylbenzene sulfonic acid salt, we have data on dodecyl benzene sulfonic acid. As suggested to us that there will be "negligible residues, if at all" for the salt or the amine base on food crops, we would find the proposal safe and suitable for regulation. The basis for safety would rest on levels of residues which would have (less than 0.05 ppm) no physiological significance. Within such use limitations we concur with the regulatory recommendations of the Petitions Evaluations Branch.

Krishna F. Misra, Ph.D.  
Toxicology Branch  
Pesticides Tolerances Division

cc:

GGFitznugh

JCCummings ✓

Perrine Sr.

Atlanta Sr. (Lewis)

PRG

VM-300

PP #1F -1052

KFMisra/ccw

4/26/71

AG/Int: GJH:itmore

4/23/71

End  
of  
Document

Washington, D. C. 20460

*File PP #1F052*

February 5, 1971

AF 11-128

PP #1F1052. Proposed exemption under CFR §120.1001(d) for the surfactant "N-(aminoethyl) ethanolamine salt of dodecylbenzene sulfonic acid."

Division of Regulations and Petitions Control  
and Division of Toxicology

The Witco Chemical Company proposes that the surfactant, N-(aminoethyl) ethanolamine salt of dodecylbenzene sulfonic acid, as one component of a multi-component emulsifier used in herbicide formulations, be exempt under the provisions of §120.1001(d). (Now designated §420.1001).

#### Discussion and Recommendations

The petitioner has not submitted any residue data nor an analytical method for residues in foods. Therefore, we are unable to state with any assurance the usual conclusions relating to residues to be expected in crops, adequacy of the analytical method, persistence in soils, or status under §420.6(a). However, in view of the small amounts of the adjuvant which would be applied (calculated value of 0.32 mg per square foot of field surface) and the pattern of uses described in Section F (pre-emergence or very early in the growing season), we believe that residues in harvested crops would be in the negligible range, if present at all.

The emulsifier is intended for use in some herbicide formulations, e. g., 2,4-D and 2,4,5-T, which are registered for use on pasture grasses or small grains. Since these crops may be grazed early the possibility is noted that some small residues could occur on the forages. There are no forage warnings.

In the absence of residue data, any recommendation in favor of the proposed exemption would be based almost entirely on toxicological considerations. This would be consistent with the exemptions previously granted for various alkyl amine and alkanol amine salts of alkyl benzene-sulfonic acids (FR 2/20/70). Our files indicate that these exemptions were granted informally (no petition) without residue data or methodology, primarily on the basis of toxicological considerations. Unless there are some toxicological properties of the N-(aminoethyl) ethanolamine not in common with those of the amine salts presently regulated, it would seem that this salt could be added to §420.1001(d).

PP #1F1052 - Page 2

It should be noted that the amine salts presently listed in 8420.1001(d) are not restricted as to use pattern whereas the present proposal (section F) would limit the use to "pre-emergence or very early in the growing season." The specimen regulation prepared for this petition (L. Terbush, 10/27/70) does not include this limitation on the use. In our opinion, it should be included in the regulation, even though it is somewhat inconsistent with the present Regulation on the other amine salts.

William S. Cox

Joseph G. Cummings  
Petitions Evaluations Branch  
Environmental Protection Agency

cc: BF-148  
CF-30  
BF-216  
PP #1F1052

WSCox/JGCummings/erk  
February 5, 1971

RD/Init/JWolff

End  
of  
Document

ENVIRONMENTAL PROTECTION AGENCY

9-PP-1F1052

Certification of Usefulness  
Pesticide Petition 1F1052  
Drew M. Baker  
BF-320

JAN 19 1971

We have examined the subject petition and related data, proposing an exemption from the requirement of a tolerance for the emulsifier N (aminoethyl)ethanolamine salt of dodecylbenzene sulfonic acid, when used to modify the emulsification behavior of other components of emulsifiers used in herbicide formulations.

We certify that this emulsifier is useful in pesticide formulations as proposed.

Charles L. Smith  
Head, Petitions  
Control Section

EPA:PR:CLSmith:cm 1-18-71

JAN 21 1971

BF-216

450 MAY 3/7/71

*[Handwritten signatures and initials]*  
Burr  
W. Hoff  
Cot  
Eli. PPT  
1F1052

DATE 10-29-70TO : BF-216  
BF-148FROM : Div. of Regulations and Petitions Control (BF-320)  
Office of ComplianceSUBJECT: Evaluation of Pesticide Petition No. 1F1059

We are transmitting herewith a copy of the pertinent sections from this petition which requests <sup>exemption</sup> ~~tolerance~~ for an emulsion on all ~~the~~ r. a. c.'s

We are also transmitting a copy of the filing letter dated 10-29-70. Assuming that USDA will take 30 days to issue a certification of usefulness and an opinion on the residue, we will need your complete evaluation by 1-12-71 in order to meet the statutory deadline on this petition.

cc: BF-320 BF-301 (Mr. Ramsey)

2

End  
of  
Document

TO: Jack Wolff - USGxDate: 11/15/70Petition No. : 1F1052 is assigned to you for review.

(1) To help us decide as soon as possible on a method tryout, please indicate before \_\_\_\_\_ (date), if there are any major deficiencies in the data of this petition and whether or not a tryout is needed.

(2) To meet permanent petition deadlines, complete and submit your review to your team leader within 45 days, in this case by 12/20/70 (date).

Your team leader will, in his turn submit it for final approval within the following 10 days, i.e. by 12/30/70 (date).

(3) To meet amended petition, temporary petition or 408e petition deadline complete and submit your review to your team leader within 30 days, i.e. by \_\_\_\_\_ (date). Your team leader will submit it for final approval within the following 5 days, i.e. by \_\_\_\_\_ (date).

tentative 45- DDL is 1/12/71

Initial, date and show this form to your team leader and to G.J. Beusch.

G.J. Beusch

10/15/68

End  
of  
Document

BF-216

October 29, 1970

Pesticide Petition No. 1F1033

Mr. M. M. Gladstone, Vice President  
Technical Liason, Organics Division  
Witec Chemical Corporation  
400 North Michigan Avenue  
Chicago, Illinois 60611

Dear Mr. Gladstone:

We have your letter of October 9, 1970, transmitting three copies of a petition requesting establishment of an exemption from requirement of tolerances for residues of the emulsifier N-(amino-ethyl) ethanediimine salt of dodecylbenzene sulfonic acid when used in liquid emulsifiable herbicide concentrates. We acknowledge receipt of your check for \$3,000 which accompanied the petition.

The petition has been designated Pesticide Petition No. 1F1033 and it is being filed today. Further action awaits completion of scientific review and evaluation.

Sincerely yours,

Lee S. TerBush  
Division of Regulations and  
Petitions Control  
Office of Compliance  
Bureau of Foods and Pesticides

cc:

Pesticides Regulation  
Division, ARS, USDA

BF-320 BF-148 BF-216 BF-300  
CA-120 (Miss Pellegrin)

LETerBush:man 10/29/70; mbc 10/23/70  
R/D Init:DMBaker 10/27/70

2

End  
of  
Document

BF-215

PESTICIDE PETITION RESUME

PETITION NO.: 1F1052

DATE RECEIVED: 10-15-70

PETITIONER: Witco Chemical Corp.

COMMON NAME OF PESTICIDE: None

TRADE NAME: None

GENERAL USE: Emulsifier in pesticide formulations

NATURE OF REQUEST: Establish exemption from requirement of a tolerance.

RELATED PETITIONS: None

SECTION A:

1. Chemical name: N-(aminoethyl)ethanolamine salt of dodecyl-benzene sulfonic acid
2. Ingredients
  - (a) Technical product  
Not applicable
  - (b) Formulations  
Not applicable

SECTION B:

1. When applied - pre-emergence, or very early in growing season
2. How applied - with liquid emulsifiable herbicide concentrate, at concentration of less than 1% of total formulation.

SECTION C:

1. Acute Toxicity
  - (a) Oral - summary sheet. Full report was submitted in August of 1969.
  - (b) Intraperitoneal - None
  - (c) Dermal - None
2. Sub-acute Toxicity - None
3. Chronic Toxicity - None
4. Carcinogenicity - None
5. Teratogenicity - None
6. Mutagenicity - None

Page 2 - Pesticide Petition Resume

SECTION D:

1. Residue Data - None
2. Metabolism Studies - None
3. Analytical Method - the method of L.E. Brydia and H.E. Persinger,  
Analt. Chem. 39:1318-20, 1967.

SECTION E: ~~Residues in excess of proposed tolerances are not expected.~~  
*Not applicable*

<u>SECTION F:</u>	<u>R.A.C.'s</u>	<u>Proposed Tolerance</u>
	All	Exemption from tolerance

SECTION G: Reasonable Grounds in Support of the Petition.

1. Need
2. Negligible hazard

Food & Drug Officer:LETerBush:mbc

Date: 10/23/70

2-2671

BF-216

BRIEFING MEMORANDUM  
 Witco Chemical Corp.  
 Chicago, Illinois

PP No. 1F1052 - Exemption from Requirement  
 of a Tolerance for an Emulsifier in  
 Pesticide Formulations

COMMISSIONER OF FOOD AND DRUGS

1. The Witco Chemical Corporation has requested exemption from requirement of tolerances for residues of the emulsifier N-(amino-ethyl)ethanolamine salt of dodecylbenzene sulfonic acid when used in liquid emulsifiable herbicide concentrates.
2. The Pesticides Regulation Division, ARS, USDA, has certified that the emulsifier is useful in pesticide formulations.
3. The Division of Pesticide Chemistry and Toxicology finds:
  - a. The metabolism of the emulsifier is adequately delineated.
  - b. An adequate analytical method is available.
  - c. The residues will be in the order of magnitude of less than \_\_\_\_\_ parts per million.
4. The Division of Toxicology finds the proposed exemption safe and that it will protect the public health.
5. The Office of Pesticides also finds the proposed exemption safe and that it will protect the public health.
6. We recommend that the attached order be signed and published.

Lee E. TerBush, etc.

APPROVED:

F. J. McFarland, Director

L. L. Ramsey, etc.

cc: BF-320 BF-300 BF-216 BF-148  
 CF-30 RE CC-30 GC-1

LETerBush:mbc 10/23/70

End  
of  
Document

BF-216

## TITLE 21--FOOD AND DRUGS

CHAPTER 1--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

## SUBCHAPTER B--FOOD AND FOOD PRODUCTS

PART 120--TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR  
PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIESN-(AMINOETHYL) ETHANOLANE SALT OF  
DODECYLBENZENE SULFONIC ACID

A petition (PP 1F1052) was filed with the Food and Drug Administration by the Witco Chemical Corporation, 400 North Michigan Avenue, Chicago, Ill. 60611, proposing establishment of an exemption from requirement of a tolerance for residues of the emulsifier N-(aminoethyl) ethanolamine salt of dodecylbenzene sulfonic acid when used as an inert ingredient in liquid emulsifiable herbicide concentrates.

The Secretary of Agriculture has certified that this pesticide chemical is useful in pesticide formulations.

Based on consideration given the data submitted in the petition and other relevant material, the Commissioner of Food and Drugs concludes that the exemption established by this order is safe and will protect the public health.

Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408(d)(2), 68 Stat. 512; 21 U.S.C. 346a(d)(2) and under the authority delegated to the Commissioner (21 CFR 2.120), § 120.1001(d) is amended by alphabetically inserting in the list a new item, as follows:

Page 2 - N-(aminoethyl) ethanolamine salt of dodecylbenzene  
sulfonic acid

§ 120.1001(d) Exemptions from the requirement of a tolerance.

\* \* \* \* \*

(d) \* \* \*

Inert Ingredients	Limits	Uses
* * *	* * *	* * *
<u>N</u> -(aminoethyl) ethanolamine salt of dodecylbenzene sulfonic acid	To be used only in liquid emul- sifiable herbicide concentrates	Emulsifier
* * *	* * *	* * *

LETerBush:mbc 10/27/70



13544

R099513

**Chemical:** Polyoxyethylene\* castor oil \*(15-200 mol

**PC Code:** 790201

**HED File Code** 11500 *Petition Files Chemistry*

**Memo Date:** 03/18/2004

**File ID:** 00000000

**Accession Number:** 412-05-4000

**HED Records Reference Center**  
09/08/2004